August 26, 2021

The FDA did NOT grant full approval to the Pfizer shots

By Carl Schwitzer

You may have heard that the Pfizer-BioNTech COVID-19 shot received FDA approval this past Monday. Politicians, national health officials, and journalists are breathless with excitement about how this approval will finally induce the remaining "vaccine-hesitant" into stepping forward to receive their jab. The FDA even has a press release on its website about it.

There's just one problem.

If you read the actual letters that the FDA sent to Pfizer on August 23, 2021, you'll see that the FDA did no such thing. In the sense that the term "FDA approval" is generally understood, this drug is *not* approved by the FDA. It is still under EUA (Emergency Use Authorization). It is still an experimental drug.

The FDA sent two letters. The first one was a letter of BLA (Biologics License Application) approval, and the second was a letter of EUA extension to COMIRNATY.

The BLA approval letter approves Pfizer's application for a license to label its COVID-19 drug with the brand name COMIRNATY. This letter also spells out the terms and requirements for nine additional clinical trials over five years, and yearly status reports, to study the acknowledged occurrences of myocarditis and pericarditis that have followed the administering of the Pfizer shots. This license to label

and manufacture is not a full approval of the drug, which clearly is still subject to many years of clinical trials.

The EUA extension letter extends the term of the EUA for the current drug and authorizes (licenses) the experimental use of the brand-name drug COMIRNATY. In the first paragraph on page 2, this letter references the license approval letter. In the second paragraph on page 2, the August 12 EUA is re-issued to include the name-branded drug in the emergency use authorization, and to add "language regarding warnings and precautions related to myocarditis and pericarditis." In the last paragraph on page 4, the EUA nature of the drugs is re-iterated, and COMIRNATY is additionally authorized for use for individuals aged 12 through 15 years.

The mRNA gene therapy shots are still experimental. Mandating them is still wrong — by a wide variety of ethical standards.

Dr. Meryl Nass, M.D. found the truths that the FDA buried in the blather of these letters and offers a theory about why it was done this way. The drug-manufacturers were granted immunity from liability for the drugs produced under the EUAs. The granting of the license re-applies the customary liability for injury and death caused by the product. Pfizer, the health officials, and the politicians get to take a fictitious victory lap for the "approval," while Pfizer-BioNTech continues to stealthily enjoy immunity from product liability because there are many millions of the unlicensed doses on the shelves and in the manufacturing pipeline that will be administered first. The licensed version will not arrive on shelves or be jabbed into arms for many months to come.

Of great concern, considering the factual content of the FDA EUA letters to Pfizer, is the breezy way the press release on the FDA website repeatedly uses the words "approve" and "approval" in reference to the Pfizer drug. If only there were a word for intentionally saying things to the public that do not match reality...

COMIRNATY seems like an unusual name for anything, much less a cutting-edge-technology gene therapy. Out of idle curiosity, I ran the name through an anagram solver. For a result, it gave TIROMANCY, which is divination or prophecy by examining how curds form during the coagulation of cheese. How apropos. That's something I'm willing to try for forecasting the results of the next election!

August 27, 2021

Did the FDA Pull a Bait-and-Switch on the American People?

By Steve McCann

On August 23rd all the mainstream or agitprop media outlets were trumpeting the news that the FDA had granted permanent approval for the Pfizer Covid-19 vaccine. The press breathlessly reported that vaccine mandates were now legal for healthcare workers, employees in private industry, college students, and government employees at all levels including teachers and school staff.

Almost immediately Joe Biden shuffled his way to the podium and read off his teleprompter that all businesses should immediately institute vaccine mandates. The Pentagon announced that vaccinations would be mandatory for all active service members. Bill de Blasio immediately instituted a vaccine mandate for all New York City teachers and staff.

But what the agitprop media and the Biden White House failed to report is that there are two critical issues as to whether the Pfizer-BioNTech Covid vaccine (which is what has been and continues to be

administered) can be mandated and whether Pfizer can be held liable for injuries, a provision that accompanies permanent approval of a vaccine or drug.

What the FDA approved and licensed is Pfizer's **Comirnaty Covid vaccine** **not** the **current** Pfizer-BioNTech **Covid vaccine** in use under an Emergency Use Authorization (EUA). The FDA has acknowledged that Pfizer has insufficient stocks of the newly licensed **Comirnaty vaccine** available but there is a significant amount of the Pfizer-BioNTech Covid vaccine available under the EUA still on hand.

Further, the FDA decreed that the Pfizer-BioNTech vaccine should remain unlicensed and under the EUA but can be used interchangeably with the newly licensed **Comirnaty vaccine**. More importantly, the FDA states that the licensed **Comirnaty vaccine** and the existing Pfizer-BioNTech vaccine are "legally distinct" but proclaims that their differences do not "impact safety or effectiveness." [emphases added]

Per the Children's Health Defense Fund:

> There is a huge real-world difference between products approved under EUA compared with those the FDA has fully licensed.
>
> EUA products are experimental under U.S. law. Both the Nuremburg Code and federal regulations provide that no one can force a human being to participate in this experiment. Under 21 U.S. Code Sec.360bbb-3(e)(1)(A), "authorization for medical products for use in emergencies," it is unlawful to deny someone a job or an education because they refuse to be an experimental subject. Instead, potential recipients have an absolute right to refuse EUA vaccines.
>
> U.S. laws, however, permit employers and schools to require students and workers to take licensed vaccines.

EUA-approved Covid vaccines have an extraordinary liability shield under the 2005 Public Readiness and Preparedness Act. Vaccine manufacturers, distributors and government planners are immune from liability. The only way an injured party can sue is if he or she can prove willful misconduct, and if the U.S. government has also brought an enforcement action against the party for willful misconduct. No such lawsuit has ever succeeded.

At least for now, the Pfizer **Comirnaty** vaccine has no such liability shield. A vial of the branded product that says "**Comirnaty**" on the label is subject to the same product liability laws as any other product. People injured by the vaccine could potentially sue for damages. Based on what has been reported over the past six months regarding Covid vaccine side effects, the potential jury awards could be astronomical.

Thus, it is highly unlikely that Pfizer will allow any Americans to take the **Comirnaty** labeled vaccine until it can coerce Congress or the Biden Administration to somehow arrange immunity for the product.

Meanwhile, Pfizer has been given the green light by the FDA to continue administering the Pfizer-BioNTech Covid vaccine under the EUA. And given the fact that they have a huge inventory on hand, they will continue to do so in any vaccine mandates.

The obvious and inevitable question is: did the FDA cynically pull a bait-and-switch on the American people by announcing permanent approval of a Pfizer Covid vaccine, which everyone would assume to be for the vaccine currently in universal use, in order to abet the Biden Administration in imposing illegal vaccine mandates?

Or, more cynically, did the FDA also conspire with Pfizer to allow them to unload their current massive inventory of a vaccine that science and the Vaccine Adverse Events Reporting System (VAERS) have exposed

as unreasonably dangerous as physicians, families, and injured vaccine recipients have reported more than 600,000 vaccine injuries. And which has also been rendered obsolete by the Delta variant, requiring a "booster" shot that has yet to be tested or approved by the FDA.

Since the beginning of the Chinese Coronavirus pandemic, the entirety of the federal medical bureaucracy has been woefully inconsistent in their pronouncements, inevitably wrong in their prescribed actions, subservient to political pressure from Democrat party politicians, and far too cozy with pharmaceutical companies as they focused solely on vaccines and not therapeutics and prophylactics.

But on the surface, these dubious actions by the FDA go far beyond incompetence. The time has come for some genuine transparency and honesty from the FDA on how this Pfizer vaccine approval came about and why in such an inordinately short period of time for a new and experimental vaccine with no long-term trials. This agency's credibility is at stake.

Meanwhile, Americans should decide for themselves about being vaccinated. But if someone is subject to a vaccine mandate, they should request to see if the vaccine they are about to receive is labeled the Pfizer **Comirnaty** vaccine as that is the only one licensed. If any other, that person has the legal right to refuse.